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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
TUNGATURTHI, PARITHOSH K	
ART UNIT	**PAPER NUMBER**
1643	

DATE MAILED: 04/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/775,444	COHEN ET AL.	
	Examiner	Art Unit	
	Parithosh K. Tungaturthi	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-17 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-17 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Please note that claim 16 recites "use of an amount of a human anti-IGF-IR antibody in the preparation of a composition for the treatment or prevention of a disorder.....", it is interpreted "method of treatment or prevention comprising administering an amount of a human anti-IGF-IR antibody...". Applicants cooperation is appreciated in amending the claims appropriately.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1 and 16 in part, 3-13 and 17, drawn to method of treatment or prevention of a disorder in a mammal comprising administering to said mammal an amount of a human anti-IGF-IR antibody wherein the disorder is multiple myeloma, classified in class 424, subclass 130.1, for example.

II. Claims 1, 2 and 16 in part, 3-13 and 17, drawn to method of treatment or prevention of a disorder in a mammal comprising administering to said mammal an amount of a human anti-IGF-IR antibody wherein the disorder is liquid tumor, classified in class 424, subclass 130.1, for example.

III. Claims 1, 2 and 16 in part, 3-13 and 17, drawn to method of treatment or prevention of a disorder in a mammal comprising administering to said mammal an amount of a human anti-IGF-IR antibody wherein the disorder is liver cancer, classified in class 424, subclass 130.1, for example.

IV. Claims 1, 2 and 16 in part, 3-13 and 17, drawn to method of treatment or prevention of a disorder in a mammal comprising administering to said mammal an amount of a human anti-IGF-IR antibody wherein the disorder is thymus disorder, classified in class 424, subclass 130.1, for example.

V. Claims 1, 2 and 16 in part, 3-13 and 17, drawn to method of treatment or prevention of a disorder in a mammal comprising administering to said mammal an amount of a human anti-IGF-IR antibody wherein the disorder is T-cell mediated autoimmune disease, classified in class 424, subclass 130.1, for example.

VI. Claims 1, 2 and 16 in part, 3-13 and 17, drawn to method of treatment or prevention of a disorder in a mammal comprising administering to said mammal an amount of a human anti-IGF-IR antibody wherein the disorder is endocrinological disorder, classified in class 424, subclass 130.1, for example.

VII. Claims 1, 2 and 16 in part, 3-13 and 17, drawn to method of treatment or prevention of a disorder in a mammal comprising administering to said mammal an amount of a human anti-IGF-IR antibody wherein the disorder is ischemia, classified in class 424, subclass 130.1, for example.

VIII. Claims 1, 2 and 16 in part, 3-13 and 17, drawn to method of treatment or prevention of a disorder in a mammal comprising administering to said mammal an amount of a human anti-IGF-IR antibody wherein the disorder

is neurodegenerative disorder, classified in class 424, subclass 130.1, for example.

IX. Claim 14 and 15, drawn to a pharmaceutical composition for the treatment or prevention of a disorder in a mammal comprising a human anti-IGF-IR antibody, classified in class 530, subclass 387.1+, for example.

3. The inventions are distinct, each from the other because of the following reasons:

The inventions of Groups I-VIII are materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success. In the instant case, Group I-VIII recite a method of treatment or prevention of a disorder in a mammal comprising administering to said mammal an amount of a human anti-IGF-IR antibody wherein the disorder is multiple myeloma, liquid tumor, liver cancer, thymus disorder, T-cell mediated autoimmune disease, endocronological disorder, ischemia, and neurodegenerative disorder respectively. These methods are different because the disorders claimed comprise distinct pathological conditions, including the differences in their modes of administration. Thus, each group differs in method objectives, method steps and parameters and in the reagents used. Further, each group is unrelated as they comprise distinct steps and utilize different products which demonstrates that each method has different mode of operation. Each invention further performs this function using structurally and functionally divergent material. Moreover, the methodology and materials necessary for detection differ significantly for each of the materials. The

examination of all groups would require different searches in the U.S. PATENT shoes and the scientific literature and would require the consideration of different patentability issues. Thus Inventions I-VIII are separate and distinct in having different method steps and different endpoints and are patentably distinct.

The inventions of Group IX and the method of Groups I-VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (i) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § 806.05(h)]. In the instant case the antibody product as claimed can be used in a materially different process such as affinity chromatography in addition to the materially different methods of Groups I-VIII.

Election of species within Group II

4. This application contains claims directed to the following patentably distinct species of the claimed invention II

If group II is elected, the applicant is required to elect one species from the following list:

Species a) acute lymphocytic leukemia

Species b) chronic milogenic leukemia

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claims are generic.

The species discussed above patentably distinct because of their distinct properties including the differences in the pathologies including modes of administration.

Election of species within Group III

5. This application contains claims directed to the following patentably distinct species of the claimed invention III

If group III is elected, the applicant is required to elect one species from the following list:

Species c) hepatoma

Species d) hepatocellular carcinoma

Species e) cholangiocarcinoma

Species f) angiosarcomas

Species g) hemangiosarcomas

Species h) hepatoblastoma

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claims are generic.

The species discussed above patentably distinct because of their distinct properties including the differences in the pathologies including modes of administration.

Election of species within Group IV

6. This application contains claims directed to the following patentably distinct species of the claimed invention IV

If group IV is elected, the applicant is required to elect one species from the following list:

Species i) thymoma

Species j) thyroiditis

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claims are generic.

The species discussed above patentably distinct because of their distinct properties including the differences in the pathologies including modes of administration.

Election of species within Group V

7. This application contains claims directed to the following patentably distinct species of the claimed invention V

If group V is elected, the applicant is required to elect one species from the following list:

Species k) Multiple Sclerosis

Species l) Rheumatoid Arthritis

Species m) Systemic Lupus Erythematosus (SLE)

Species n) Grave's Disease

Species o) Hashimoto's Thyroiditis

Species p) Myasthenia Gravis

Species q) Auto-Immune Thyroiditis, Bechet's Disease

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claims are generic.

The species discussed above patentably distinct because of their distinct properties including the differences in the pathologies including modes of administration.

Election of species within Group VI

8. This application contains claims directed to the following patentably distinct species of the claimed invention VI

If group VI is elected, the applicant is required to elect one species from the following list:

Species r) Type II Diabetes

Species s) hyperthyroidism

Species t) hypothyroidism

Species u) thyroiditis

Species v) hyperadrenocorticism

Species w) hypoadrenocorticism

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claims are generic.

The species discussed above patentably distinct because of their distinct properties including the differences in the pathologies including modes of administration.

Election of species within Group I-VI

9. This application contains claims directed to the following patentably distinct species of the claimed invention I-VI

If group I-VI is elected, the applicant is required to elect one species from the following list:

Species i) corticosteroid

Species ii) anti-emetic

Species iii) cancer vaccine

Species iv) analgesic

Species v) anti-vascular agent

Species vi) anti-proliferative agent

AND

Species vii) GM-CSF DNA and cell-based vaccines

Species viii) dendritic cell vaccines

Species ix) recombinant viral vaccines

Species x) heat shock protein (HSP) vaccines

Species xi) allogeneic

Species xii) autologous tumor vaccines

Species xiii) rhuMAb-VEGF

AND

Species xiv) farnesyl protein transferase inhibitors

Species xv) alpha.v.beta.3 inhibitors

Species xvi) alpha.v.beta.5 inhibitors

Species xvii) p53 inhibitors

Species xviii) PDGFR inhibitors

AND

Species xix) 2.12.1

Species xx) 2.13.2

Species xxi) 2.14.3

Species xxii) 4.9.2

Species xxiii) 4.17.3

Species xxiv) 6.1.1

AND

Species xxv) VH DP-35

Species xxvi) VIV-4/4.35

Species xxvii) VH DP-47

Species xxviii) VH DP-71

AND

Species xxix) A27

Species xxx) A30

Species xxxi) O12

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 3, 4, 6, 13 and 17 are generic.

The species discussed above patentably distinct because of their distinct properties including the differences in their structure and function, in addition to their pathologies and modes of administration.

Election of species within Group IX

10. This application contains claims directed to the following patentably distinct species of the claimed invention IX

If group IX is elected, the applicant is required to elect one species from the following list:

Species a1) multiple myeloma

Species b1) liquid tumor

Species c1) liver cancer

Species d1) thymus disorder

Species e1) T-cell mediated autoimmune disease

Species f1) endocrinological disorder

Species g1) ischemia

Species h1) neurodegenerative disorder

AND

Species i1) anti-emetic

Species j1) cancer vaccine

Species k1) analgesic

Species l1) anti-vascular agent

Species m1) anti-proliferative agent

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claims are generic.

The species discussed above patentably distinct because of their distinct properties including the differences in the pathologies including modes of administration.

11. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims

readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

12. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Furthermore, because these inventions are distinct for the reasons given above and the search required for one group is not required for another group, restriction for examination purposes as indicated is proper.

13. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product

claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

14. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Parithosh K. Tungaturthi whose telephone number is 571-272-8789. The examiner can normally be reached on Monday through Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

16. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,
Parithosh K. Tungaturthi, Ph.D.
Ph: (571) 272-8789

LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER